

SB
SmithKline Beecham
Consumer Healthcare

November 4, 1997

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

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Dear Sir/Madam:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that SmithKline Beecham Consumer Healthcare, Pittsburgh, PA 15230, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM

"Promotes emotional well-being"

"This formula can be used as a dietary supplement to work to help you maintain a healthy mood."

"... St. John's Wort, which is in Abtei Mood, is well researched, with clinical trials showing benefits in maintaining normal emotional balance and well-being."

NAME OF INGREDIENT OR SUPPLEMENT THAT IS SUBJECT OF CLAIM

St. John's Wort (*Hypericum perforatum*)(Leaf) Extract

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

Abtei Mood

The undersigned certifies that the information contained in this notice is complete and accurate and that SmithKline Beecham Consumer Healthcare has substantiation that the statements are truthful and not misleading.

If you have any questions, feel free to contact me at (973) 631-8179 or at the address below.

Sincerely,



Sue E. James
Associate Director, Regulatory Affairs

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